

RESPONSE

Claim Rejections under 35 U.S.C. § 102(e).

Claims 1 and 21 stand rejected under 35 U.S.C. § 102(e) ("Section 102(e)") as anticipated by U.S. Pat. No. 6,438,426 to Hofstad ("Hofstad").

An invention is unpatentable under Section 102(e) if "the invention was described in . . . a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent." A Section 102(e) rejection is only appropriate, however, where "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." See *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). For the reasons set forth below, Applicant submits that the reference cited by the Examiner does not teach each and every element of the claimed invention, as amended, and thus does not anticipate the present invention.

Applicant's claim 1, as amended, recites "a switch to electrically couple the second end of each electrode either to the defibrillator or to the monitoring device." Applicant finds no mention of this limitation in Hofstad.

Rather, Hofstad teaches a coronary sinus catheter that includes a plurality of distal electrodes and a proximal electrode portion. See Abstract. A control unit 14 including a switch 82 is attached to the catheter in order to switch the electrical configurations of the distal electrodes. See col. 3, ln. 50-57; col. 4, ln. 27-34. "Control unit 14 permits operating ring electrode pairs 35, 36, 38, 40, and 42 independently for cardiac mapping or pacing, or together in series to act as a single electrode for defibrillation/cardioversion." Col 3, ln. 54-57. The described "cardioversion

mode” refers to the control unit switch position that allows the distal electrodes to operate in series.

Whereas, the “monitoring/diagnostic mode” refers to the control unit switch position that allows the distal electrodes to operate independently. These “modes” do NOT refer to actually performing cardioversion or monitoring but rather facilitating these processes. The switch or control unit disclosed in Hofstad merely controls the electrical arrangement between the distal electrodes but does not provide for the external switching between a monitoring device or a defibrillator. Exhibit A is provided as an example of the control unit or switch disclosed in Hofstad. As illustrated, the switch merely controls whether the distal electrodes are connected in series or connected individually. This switching device configures the catheter for the external connection of either a monitoring device OR a defibrillator with the disclosed coronary sinus catheter, but does not directly switch an electrical connection between the two different devices.

The switch claimed in the present invention “electrically couples” the intracardiac electrodes to a monitoring device or a defibrillator device depending on the position of the switch. Therefore, the switch 82 and control unit 14 disclosed in Hofstad, fail to anticipate the switch claimed by the present application.

As Hofstad fails to teach each and every element as set forth in claim 1 of the present application, Hofstad fails to anticipate the present invention under Section 102(e). In addition, claim 21 is indirectly dependent from claim 1, and thereby includes all of the limitations of claim 1. Therefore, claim 21 should be allowable for at least the same reasons as claim 1. Accordingly, Applicant respectfully requests withdrawal of the rejection of claims 1 and 21 under Section 102(e).

Claim Rejections under 35 U.S.C. § 103.

Claims 2-5, and 7 stand rejected under 35 U.S.C. § 103(a) ("Section 103") as unpatentable over Hofstad.

An invention is unpatentable under Section 103 "if the differences between the subject matter sought to be patented over the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains."

To establish a *prima facie* case of obviousness, three criteria must be met. "First, there must be some suggestion or motivation . . . to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2142.

"Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *In re John R. Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992). Any such suggestion must be "found in the prior art, and not based on applicant's disclosure." *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

A "clear and particular" showing of the suggestion to combine is required to support an obviousness rejection under Section 103. *Id.* For the reasons set forth below, Applicant submits that the prior art fails both to teach or suggest all the claim limitations, and to clearly and particularly suggest the combination indicated by the Examiner; thus, Applicant's claims are not obvious in view of the prior art references.

As discussed above, Applicant's claim 1 recites "a switch to electrically couple the second

end of each electrode either to the defibrillator or to the monitoring device.” As Hofstad fails to disclose or suggest such a switch, Hofstad fails to either anticipate or render obvious the present invention.

Indeed, as discussed above with reference to Section 102(e), the switch disclosed by Hofstad operates solely to control the nature of electrical interconnection between the distal electrodes on a catheter. In this manner, Hofstad requires only one catheter to process information and/or to perform cardioversion/defibrillation. Hofstad, however, neither discloses nor suggests a switch capable of electrically coupling the catheter, or an electrode contained thereon, to either a defibrillator or a monitoring device. Rather, Hofstad teaches a single catheter capable of performing functions that previously required more than one catheter. Hofstad fails to speak to any novel or innovative way of selectively connecting the single catheter to either a defibrillator or monitoring device. Hofstad merely mentions that “the control unit 14 includes known circuitry for electrophysiology, pacing, and cardioversion/defibrillation.” Col 3, ln. 49-50. Thus, Hofstad relies on prior art methods of disconnecting and reconnecting the disclosed single catheter to a defibrillator or monitoring device as necessary.

As Hofstad neither discloses nor suggests a switch capable of electrically coupling an electrode to either a defibrillator or a monitoring device, and thus fails to disclose or suggest all of the present claim limitations, Hofstad fails to render obvious the present invention as claimed in claim 1.

As claims 2-5, and 7 further depend from claim 1, they are allowable for at least the same reasons as described above with reference to claim 1.

In light of the foregoing, Applicant respectfully requests withdrawal of the rejections of

claims 2-5, and 7 under Section 103.

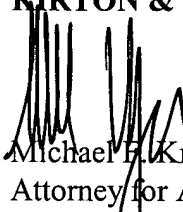
Allowable Subject Matter

Examiner objects to claim 6 but recognizes that claim 6 would be allowable if rewritten to include the limitations of the base claim. Applicant respectfully requests withdrawal of the objection to claim 6 in light of the discussion above.

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Respectfully Submitted,

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Exhibit A



Device:

Monitoring device
(monitor any individual
electrode)

OR

Defibrillator
(switch on D, E, F, G
so that proximal
electrodes are in
series)

Control Unit

Proximal
Electrode

Distal
Electrodes

